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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,386	03/06/2008	Jane Shelby	21101.0050U2	3875
23859	7590	02/14/2011	EXAMINER	
Ballard Spahr LLP			KIM, TAEYOON	
SUITE 1000				
999 PEACHTREE STREET			ART UNIT	PAPER NUMBER
ATLANTA, GA 30309-3915			1651	
			MAIL DATE	DELIVERY MODE
			02/14/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,386	Applicant(s) SHELBY, JANE	
	Examiner Taeyoon Kim	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 10-12, 17-26 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 17-24 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-12, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment and response filed on 1/7/2011 has been received and entered into the case.

Claims 4-9, 13-16 and 27-29 are cancelled, claims 30-32 are newly added, and claims 17-24 and 30-32 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-3, 10-12, 25 and 26 have been considered on the merits. All arguments have been fully considered.

Claim Objections

The claim objection to claim 10 has been withdrawn due to the amendment.

Claim Rejections - 35 USC § 112

The claim rejection under 35 U.S.C. § 112 to claims 5 and 25-29 has been withdrawn due to the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation directed to the skin being preserved at a temperature above or below freezing disclosed in claims 11 and 12 does not clearly point out whether this step of preserving

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at the disclosed temperature being carried out with the skin in the composition, or the composition comprises the skin previously preserved under the disclosed condition. Clarification is required.

Claim Rejections - 35 USC § 102

The claim rejection under 35 U.S.C. § 102 based on Guienne et al. has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. § 102 based on Alkemade et al. has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. § 102 based on Lindstrom et al. has been withdrawn due to the amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 10-12, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce et al. (1993; Plast. Reconstr. Surg.; IDS ref.).

Boyce et al. teach composite grafts of cultured skin cells (epidermal keratinocytes and dermal fibroblasts; skin grafts; thus considered as a sheet) and glycosaminoglycan, and since the skin cells or skin grafts are cultured in serum-free medium, the composite is considered without serum.

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With regard to the limitation directed to the intended use of the composition being for preserving cells (claim 3), this limitation does not provide any weight to the claimed composition since it does not provide any structural limitation. Nevertheless, the cultured skin grafts are kept as intact (alive) for skin grafting (skin transplantation) to treat wound, it is interpreted that the composite of Boyce et al. is capable to preserve skin.

The limitation of claims 11, 12 and 26 is considered as the skin being preserved at above freezing temperature in the composition. This limitation is directed to a process of using the claimed composition, and thus, this limitation does not provide any structure to be considered for the claimed composition.

With regard to the limitation of claim 10, the composition of Boyce et al. does not disclose any non-cell penetrating cryoprotectant and thus, it is considered not to contain a non-cell penetrating cryoprotectant.

Thus, the reference anticipates the claimed subject matter.

Claims 1-3, 10-12, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cram et al. (1983, J. Trauma; IDS ref.) in light of Fraser et al. (1997, J. Intern. Med.; IDS ref.).

Cram et al. teach human skin stored at 4°C in RPMI tissue culture medium in the absence of serum for preserving human skin (abstract; Table 1; RPMI-low).

Since the human skin inherently contains hyaluronic acid or hyaluronan as taught by Fraser et al. (see Table 2), the human skin stored in RPMI-low of Cram et al. anticipates the claimed invention.

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The limitation of claims 11, 12 and 26 is considered as the skin being preserved at below or above freezing temperature in the composition. This limitation is directed to a process of using the claimed composition, and thus, this limitation does not provide any structure to be considered for the claimed composition. Nevertheless, as discussed above, Cram et al. teach the limitation of claims 11 and 26. Furthermore, the composition of Cram et al. is certainly capable of being frozen.

Thus, the reference anticipates the claimed subject matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651